

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 30-43 and 51-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 5, 2007.

Claims 44, 46-50 and 57-79 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 20, 2007 was filed after the mailing date of the non-final Office action on May 31, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. However, both U.S. Patent documents were not considered since the citation lacked the inventors name(s).

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

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the references have been cited by the examiner on form PTO-892, they have not been considered.

Response to Arguments

Applicant's arguments, see responses, filed on December 3, 2007 and March 11, 2008, with respect to the rejection(s) of claim(s) 44, 45-50, 58 and 59 under 35 U.S.C. 102 (e) and claims 44, 45-50 and 57-59 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shinohara et al. (US Pat. 6,750,052).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite incomplete method steps. The claims depend from claim 44, drawn to a method that screens molecules for antiviral activity. After completing the steps of claim 44, molecules have been screened for the detection of an interaction with LEDGF/P75. The methods of claims 48-50 skip to the use of those molecules in other assays. For example, claim 48 is drawn to monitoring the prevention or suppression of retroviral replication or integration. The method steps are not complete because there is no step that bridges the detection of an interaction between the candidate molecule and LEDGF/P75 with an assay that monitors retroviral replication or integration. Such an assay requires the selection of molecule

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(from claim 44) and steps for using that molecule in an assay for monitoring retroviral replication/integration. The same logic applies to claims 49 and 50, both of which recite method steps that are not clearly linked to the outcome of claim 44. With regard to claims 57-59, it is not clear when the recited methods steps take place in relation to the method steps of claim 44.

While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination. Correction is required.

Claim Rejections - 35 USC § 102

Claims 44 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Shinohara et al. (US Pat. 6,750,052).

The claimed invention is drawn to a method of screening molecule(s) for their antiviral activity comprising the step of exposing said molecules to the protein LEDGF/P75 or a fragment thereof and determining the interaction of said molecule(s) with said protein LEDGF/P75. The method further comprises the step of determining the binding of said molecule(s) to said protein LEDGF/P75. The only active steps are that of exposing molecules to a LEDGF/p75 protein or a fragment thereof, determining the interaction of said molecule(s) with said protein and then determining of the molecule(s) bind to LEDGF/p75 or fragments thereof. According to the method, these steps result in screening for antiviral activity.

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Shinohara et al. teach the analysis of antibodies against LEDGF by exposing LEDGF to sera from a subject and determining if these antibodies are present in the sera with a kit that compares amounts of antibodies bound to LEDGF. Shinohara et al. teach that the kit comprises LEDGF and control antibodies. Therefore, even though Shinohara et al. do not discuss antiviral properties of these antibodies, the limitations of the claims have been met because antiviral activity is simply determined by the detection of an interaction of a molecule(s) with LEDGF/P75, according to the claims. Furthermore, Shinohara et al. do anticipate the claimed invention since they teach the same active steps as summarized above. *See paragraphs 24-34.*

Claim Objections

Claims 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 44 is objected to because of the following informalities: the claim recites, "...protein LEDGF/p75 or a fragment thereof...", but only refers to the protein LEDGF/p75 and not the fragments thereof further in the claim. This trend is also observed in claims 46, 47, 58 and 59. Appropriate correction is required.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
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